REMARKS

The status identifiers have now been added with this resubmission. No other changes have been made.

Claims 1-15 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to use claim phrasing which clearly defines the scope of the claims.

Claims 1-16 and 18-20 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,952,370 to Cummings, *et al.* ("Cummings").

Claim 17 stands rejected under 35 U.S.C. §103(a) as unpatentable over Cummings in view of U.S. Patent No. 5,525,295 to Pflug, *et al.* ("Pflug").

Finally, double-patenting rejections have been entered against the pending claims in view of the claims in co-pending applications Ser. Nos. 10/363,546, 10/759,071 and 10/804,292.

1. The § 112, Second Paragraph Rejection Has Been Addressed.

The Applicants have amended claim 1 to use an appropriate "comprising" format. This amendment is made solely as a matter of altering the claim format as requested, without intent to alter the scope of the pending claims in any manner.

Reconsideration and withdrawal of the pending § 112 rejection is respectfully requested.

2. The Claims Are Patentable Over Cummings.

The Applicants respectfully traverse the rejections based on Cummings, on the grounds that this reference does not disclose or suggest the features of the present invention for which it is cited.

The Present Invention: The present invention provides a novel approach to sterilizing objects in a rapid and highly efficient manner, and does so without the need for any transport gas. Specifically, an aqueous hydrogen peroxide solution is abruptly expanded into a sterilization chamber, and the resulting over-saturation condition causes nearly instantaneous formation of a condensate film on the surfaces of the objects to be sterilized. This unique approach allows for *extremely rapid* sterilization *without the need to input any additional heat energy*. Instead, sterilization occurs as the heat of evaporation is released (*i.e.*, enthalpy change on condensation). Following the abrupt condensation (*e.g.*, after only 3 seconds), the chamber may be quickly evacuated to evaporate the condensate layer. In order to more clearly reflect these aspects of the invention, the Applicants have amended independent claim 1 to recite that the dampening step "includes abruptly releasing the steam compound into a sterilizing chamber without additional transport gas flow, so that the steam compound becomes over-saturated and condenses in the shortest possible time on the surfaces." Independent apparatus claim 16 has been similarly amended.

The present invention thus permits highly effective sterilization to be completed in a very efficient manner, achieving high production throughput rates which avoiding the expense and complication of supplying and controlling a

separate transport gas to carry the sterilizing agent, or maintaining the temperature of the sterilizing chamber surfaces at specific levels.

The Cummings Reference: In contrast to the present invention, Cummings discloses essentially continuous hydrogen peroxide injection flow into a chamber whose surfaces must be maintained at specific temperatures in order to support sterilization. Thus, Cummings teaches a process which is the antithesis of the present invention's abrupt creation of an over-saturated environment, followed shortly thereafter by evacuation of the chamber.

Cummings teaches a relatively long sterilization process, which consequently introduces a number of complications to the process. In Cummings: (i) in order for a condensation film to form on the surfaces to be sterilized, the surfaces must be initially at a temperature below that of the incoming mixture of water vapor and hydrogen peroxide (*i.e.*, gradual condensation by absorption of heat from the vapor by the cold surface); (ii) additional hydrogen peroxide must be continuously injected into the sterilization chamber in order to maintain a sufficient concentration of hydrogen peroxide on the cold surface as the hydrogen peroxide both disassociates and evaporates in the presence of a water-removing vacuum; (iii) a water-removing vacuum must be carefully maintained *between* the evaporation point of water and the evaporation point of hydrogen peroxide; and (iv) the cold surface must be continuously cooled to ensure its temperature does not rise. Cummings at 2:41-64 ("The vapor phase hydrogen peroxide is continued to be introduced into the chamber until the surfaces are sterile while preserving the temperature ranges

of both the first [10°C] and second [20°C] portions of the surfaces."); 3:47-54 (vacuum established to preferentially extract water); 3:55-60 ("injections of vapor phase hydrogen peroxide continue, thereby establishing a flow through the system"); 5:57-7:7 (full process description).

In addition to complicated steps to maintain the required environmental conditions, Cummings also disadvantageously requires considerable time to achieve the desired sterilization. *See, e.g.*, Cummings at 6:14-16 (initial vapor introduction "for approximately one minute"); 6:44-48 (subsequent additional hydrogen peroxide injections over 4 to 32 minutes).

Thus, Cummings discloses a cumbersome, time-consuming sterilization process requiring constant, careful parameter monitoring and maintenance. This reference, by relying on relatively slow condensation from a *sub-saturated* vapor, neither anticipates, nor provides any suggestion in the direction of, the present invention's sterilization by *abrupt generation* of an *over-saturated* vapor which immediately condenses on surfaces, without the need to carefully monitor or maintain surface temperatures or other environmental parameters such as the level of vacuum applied during drying. Indeed, one of the advantages of the present invention is that the drying is carried out below *both* the water and hydrogen peroxide boiling points, eliminating the need for careful control at an intermediate vacuum level.

Because Cummings neither discloses or suggests the present invention, including the present invention's dampening step which "includes *abruptly* releasing the steam compound into the sterilizing chamber ... so that the steam

compound becomes *over-saturated* and condenses in the shortest possible time on the surfaces," and a drying step which "is carried out by evacuation at a pressure below boiling points of water *and* hydrogen peroxide," the present invention is patentable over the Cumming reference under §§ 102(b) and 103(a). Accordingly, the Applicants respectfully request the pending §§ 102(b) and 103(a) rejections be reconsidered and withdrawn.

3. The Double Patenting Rejections Should Be Withdrawn.

The Applicants respectfully traverse the pending provisional double patenting rejections of the claims over claims 1-16 of co-pending Application Ser. No. 10/363,546, claims 1-18 of co-pending Application Ser. No. 10/759,071 and claims 1-8 of co-pending Application Ser. No. 10/806,292, on the grounds that these claims are patentably distinct from the present invention.

Ser. No. 10/363,546: The present claims are directed to a process and apparatus in which an *over-saturated* vapor mixture is abruptly formed in a sterilization chamber, which then immediately condenses on the surfaces of the objects to be sterilized.

The claims in co-pending Application Ser. No. 10/363,546 on the other hand, are directed to use of an under-saturated (i.e., superheated) vapor mixture, which is established in a chamber. This superheated mixture passes through a liquid-proof anti-bacterial barrier cover into a package, then condenses on a component. The sterilizing liquid film is then again put in a vapor state by evaporation to permit it to pass back out of the liquid-proof barrier cover and be withdrawn from the chamber.

The Applicants respectfully submit that this is not the "same inventive concept" as in the present invention's over-saturation-based sterilization approach, *i.e.*, no claim in the present application could be literally infringed while literally infringing a claim in the corresponding application. Accordingly, consistent with the guidance in MPEP § 804, the pending provisional double-patenting rejection vis-à-vis Application Ser. No. 10/363,546 should be withdrawn.

Ser. No. 10/759,071: The claims of this Application are directed to the use of a low-heat conducting, non-adsorptive material for the structural members (*e.g.*, walls) of the sterilization chamber, in order to minimize condensation on the chamber walls depleting the vapor volume so that the target objects in the chamber are completely sterilized. The Applicants respectfully submit that a *prima facie* showing of obviousness of either the present claims over the '071 claims, or the '071 claims over the present claims, sufficient to support the pending provisional obviousness-type double-patenting rejection, has not been made.

The present application is entirely silent as to the material of its sterilization chamber wall, and contains nothing which would suggest to one of ordinary skill that any particular wall material would be advantageous. While it is asserted in the October 21, 2004 Office Action that use of the claimed chamber materials is "intrinsic" to the present invention's over-saturation condensation process (Office Action at 6), there is nothing in the present application which suggests, nor any explanation in the Office Action as to how, the claimed process

"intrinsically" requires the use of such chamber materials. Rather, there is nothing in the record which suggests that the presently claimed process cannot be practiced in a metal-walled sterilization chamber. Moreover, there is nothing in the cited art teaching or suggesting the use of low-heat conducting, non-adsorptive materials to avoid excessive hydrogen peroxide-depleting vapor condensation away from a target surface in a over-saturation condensation process. Viewed in the opposite direction, the '071 Application teaches the use of a novel sterilization process which relies on the use of low-heat conducting, non-adsorptive chamber materials in order to ensure the sterilization process can be completed without condensation on the walls resulting in inadequate hydrogen peroxide concentrations at the surfaces of the objects to be sterilized. There is nothing in the '071 Application which teaches or suggests the use of the recited process without the recited special wall materials, or that there would be a reasonable expectation of success with such a modification to the '071 invention.

Accordingly, in the absence of any teaching or suggestion which renders either the present claims or the claims of the '071 Application obvious in view of one another, the threshold requirement for an obvious-type provisional double-patenting rejection have not been met, and this rejection should be withdrawn.

Ser. No. 10/806,292: As with '071 claims, the claims of the '292 Application are directed to a non-obvious variant of the present invention. As noted above, the present invention relies on essentially adiabatic expansion of the hydrogen peroxide vapor to generate an over-saturated mixture, and causes a target surface to be sterilized by sudden heating of the condensed mixture (*i.e.*,

the hydrogen peroxide is heated before the heat dissipates into the target, causing oxygen atoms to disassociate and become available to destroy bacteria).

Because the present claims are directed to a process which does not rely on an external heat source to cause the hydrogen peroxide, there is no teaching or suggestion in the present application for the preheating of the target objects and/or the chamber as recited in the '292 Application claims. Conversely, the '292 Application teaches a sterilization process which requires preheating to ensure the sterilization process is completely effective. In view of this disclosure, nothing is to be found in the '292 Application to suggest the present claim's sterilization process without an external heat source.

As with the '071 Application, in the absence of any teaching or suggestion which renders either the present claims or the claims of the '292 Application obvious in view of one another, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing amendments, the Applicants respectfully submit that claims 1-4, 6, 8-9, 11, 13-14, 16 and 18-19 are now in allowable form. Early and favorable consideration and issuance of a Notice of Allowance for these claims is respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029082/50057US).

Respectfully submitted,

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